

**Remarks**

The Office Action mailed 11 May 2007 has been received and reviewed. Claims 39, 45, and 58 having been amended, claims 1-38, 40, and 41 having been previously cancelled (without prejudice), and claims 65-66 having been added, the pending claims are claims 39 and 42-66. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 39, 45, and 58 have been amended to include the clarifying language “selecting a dental article form having a self-supporting structure comprising a first shape that includes a reservoir, wherein the self-supporting structure is formed from an organic composition having sufficient malleability to be formed into a second shape, wherein the organic composition gives the self-supporting structure its self-supporting and malleable characteristics.” The application as a whole supports this clarifying language.

New claims 65-66 include the clarifying language “selecting a dental article form having a self-supporting structure comprising a first shape that includes a reservoir, wherein the self-supporting structure is formed from an organic composition having sufficient malleability to be formed into a second shape, wherein the dental article form does not include slots.” The application as a whole supports this language, since no slots are described or shown in the dental article forms.

It is respectfully requested that if the amended language is not acceptable and is the only issue preventing allowance, that the Examiner call the undersigned at 612-305-1217 as Applicants would be amenable to discussing language that would address the Examiner’s concern regarding description of the composition.

**Interview Summary**

Applicants thank the Examiner for the time and consideration shown in the interview on 08 August 2007 with Applicants’ Representative Ann Mueting and Inventor Dr. Naimul Karim. During the interview, Dr. Karim showed an example of a preformed dental crown made from a organic composition having a self-supporting structure and malleability analogous to the

composition of the dental article form encompassed by the claims of the present application, as well as a two-minute video demonstrating how the composition can be manipulated by a dentist.

The preformed dental crown that was shown is available from 3M Company under the product designation "Protemp Crown Temporization Material" (e.g., lower molar, large, catalog number 50612 PROTEMP Crown). Although the product shown was not a dental article form of the present invention, the organic composition that forms the preformed dental crown is the same type of organic composition that forms the dental article form of the present invention.

The two-minute video demonstrated how the preformed malleable crown (3M's PROTEMP Crown) is used clinically, analogous to how a dental article form of the present invention could be used. The organic composition of the crown is self-supporting and malleable when the dental professional removes it from its light-protected packaging, similar to a dental article form of the present invention. First, the video showed that the preformed crown is trimmed with ordinary crown scissors to proper length and then placed on a tooth stump that was previously prepared for a full crown, similar to how a dental article form of the present invention can be adjusted in length. Then the video showed how the dental professional uses his fingers and a simple composite instrument to adapt the crown all around the gingival margin and to establish proper contacts to both proximal teeth, similar to how a dental article form of the present invention can be adjusted. The video also showed how proper occlusal adjustment to the opposing teeth is made by letting the patient bite while the crown is in the malleable state and is still on the prepared tooth stump, similar to how a dental article form of the present invention can be adjusted. The video showed that the crown was partially cured for a few seconds with a hand held dental curing light, and then removed from the patient's mouth and fully cured for a minute with a hand held dental curing light. Dr. Karim explained that this latter step may or may not be done with the dental article form of the present invention, although the hardenable dental material placed in the reservoir of the dental article form could be similarly hardened.

Applicants discussed the art, particularly Neustadter et al. As the Examiner indicated in the Interview Summary, "Neustadter shows a form that requires a physical means, slit [sic], to change shape and does not show a composition that is malleable and self-supporting." It was

pointed out that although Neustadter et al. do describe a pattern made of plastic (e.g., polyvinyl acetate, polyethylene and copolymers thereof) (col. 2, lines 40-47), and that “[t]he plastic pattern should have the characteristic of (1) softness or pliability so that it can be adapted or modified by the technician and (2) retentivity so that it retains its modified shape,” it is not clear that these desired characteristics come from the choice of materials for making the pattern or from the use of the slot means in the design of the pattern, as discussed in greater detail below.

The Examiner appeared to appreciate the significance of the claim language describing Applicants’ invention relative to the prior art. However, the Examiner suggested that the claim language might be modified to more clearly indicate that the composition itself is self-supporting and malleable, rather than the structural design of the dental article form providing the self-supporting nature and malleability. Although Applicants believe the claim language says this and does not require further clarification, particularly in view of the specification, in the interest of expediting prosecution, amendments have been presented herein.

### **The 35 U.S.C. §103(a) Rejections**

The Examiner rejected claims 39 and 42-44 under 35 U.S.C. §103(a) as being unpatentable over Simor (U.S. Patent No. 3,585,723) in view of Neustadter (U.S. Patent No. 3,565,387), Ivanov et al. (U.S. Patent No. 4,113,499) and Wilson (U.S. Patent No. 5,487,663). The Examiner rejected claims 45, 46, 48-55, 58, and 60-64 under 35 U.S.C. §103(a) as being unpatentable over Simor (U.S. Patent No. 3,585,723) in view of Neustadter (U.S. Patent No. 3,565,387) and Wilson (U.S. Patent No. 5,487,663). The Examiner rejected claims 47 and 59 under 35 U.S.C. §103(a) as being unpatentable over Simor (U.S. Patent No. 3,585,723) in view of Neustadter (U.S. Patent No. 3,565,387) and Wilson (U.S. Patent No. 5,487,663) as applied to claim 45, and further in view of Ivanov et al. (U.S. Patent No. 4,113,499). The Examiner rejected claim 56 under 35 U.S.C. §103(a) as being unpatentable over Simor (U.S. Patent No. 3,585,723) in view of Neustadter (U.S. Patent No. 3,565,387) and Wilson (U.S. Patent No. 5,487,663) as applied to claim 45, and further in view of Uthoff (U.S. Patent No. 5,102,332). The Examiner rejected claim 57 under 35 U.S.C. §103(a) as being unpatentable over Simor (U.S.

Patent No. 3,585,723) in view of Neustadter (U.S. Patent No. 3,565,387) and Wilson (U.S. Patent No. 5,487,663) as applied to claim 45 above, and further in view of Kahn (U.S. Patent No. 3,949,476).

Each of these rejections is traversed; however, in the interest of expediting prosecution, claims 39, 45, and 58 have been amended to clarify that the organic composition that forms the dental article form itself is self-supporting and malleable. Thus, these rejections are rendered moot. Insofar as the prior art applies to the presently pending claims, the following comments are provided.

Simor describe a crown, however, the major focus of the disclosure is on the use of metal as a material forming the crown to allow for reshaping by bending (e.g., bending the lower edge portion of the crown inwardly at col. 6, lines 55-58, or bending by the opposing occlusal surface at col. 8, lines 60-71). Brief reference is also made to the use of a plastic for forming the crown (e.g., col. 3, lines 68-72). However, the general term “plastic” can refer to a wide variety of materials, including those that are elastic and return to their original shape after deformation.

The Examiner uses Neustadter et al. for the disclosure of an organic composition for making a pattern for a dental article. Although Neustadter et al. do describe the use of a plastic such as “polyvinyl acetate, polyethylene and copolymers thereof” (col. 2, lines 45-47), which may or may not be malleable, and the desire to select materials having a shore A hardness of about 70 (col. 2, lines 56-57), which may or may not be malleable, there is no specific and enabling disclosure of an organic composition that is itself self-supporting and malleable.

Neustadter et al. describe dental patterns that include slot means for reshaping the pattern (e.g., col. 2, lines 11-16, “[t]he slot is relatively substantial width so that the width of the pattern can be narrowed sufficiently by pressing the edges together to partially or even fully close the slot the required amount to fit the prefabricated pattern into the space between the sides of the abutting or adjacent teeth”). Thus, Neustadter et al. show a form that requires a physical means, a slot, to change shape. With respect to the use of the plastic materials discussed above, Neustadter et al. state that “[t]he plastic pattern should have the characteristic of (1) softness or pliability so that it can be adapted or modified by the technician and (2) retentivity so that it

retains its modified shape” (col. 2, lines 52-55, emphasis added). Although this describes reshaping and retaining the shape, it is not clear that these desired characteristics come from the choice of materials for making the pattern (i.e., the selection of the plastic) or from the use of the slot means in the design of the pattern, particularly when the document is read as a whole. Simple reference to polyvinyl acetate, polyethylene and copolymers thereof does not necessarily provide sufficient description for one of skill in the art to select a composition that is both self-supporting and malleable. Thus, Neustadter et al. do not show a composition that is malleable and self-supporting.

Furthermore, the pattern of Neustadter et al. is not used in a patient’s mouth with a hardenable dental material in the reservoir. That is, there is no teaching or suggestion that “the dental article form is reshaped while in the subject’s mouth before or after filling the reservoir with the hardenable dental material,” as recited in each independent claim.

Although Ivanov et al. disclose a surfactant mixed in a disposable mold form, Ivanov et al. is directed to molds used in the foundry industry, a completely nonanalogous technology area.

The Examiner acknowledged that this combination of three documents (Simor in view of Neustadter et al. and Ivanov et al.) for the rejection of claims 39 and 42-44, or just the combination of Simor in view of Neustadter et al. for the rejection of claims 45-64, does not teach or suggest each of the steps recited in Applicants’ claimed method (e.g., pages 3 and 4, Final Office Action). Thus, the Examiner cited Wilson for a disclosure of removing the dental article form from the dental article; however, Wilson does not teach that the dental article form is self-supporting and malleable. Furthermore, Wilson state that “it is an important feature of the present invention that the side wall, or walls, 20 are essentially straight, as contrasted to existing art wherein the sidewalls have a distinct negative draft” (col. 3, lines 61-64, emphasis added). That is, straight sidewalls are seen as necessary for removal of the form. Neither Simor nor Neustadter et al. disclose dental article forms with straight sidewalls.

It is respectfully submitted that each of the elements of the claimed invention is not shown in the cited documents, but even if they were, there is no motivation to combine the cited documents. Even if there were such motivation to combine them, there is no enabling teaching

or suggestion of a dental article form that is formed from an organic composition, wherein the organic composition is itself both self-supporting and malleable, wherein the organic composition is in the form of a self-supporting structure that includes a reservoir as a container to hold a hardenable dental material, and further wherein the dental article form can be used in the patient's mouth and reshaped while in the patient's mouth.

It is submitted that the rejections may only be made by impermissible hindsight reconstruction, that is, by picking and choosing from each document that which supports these rejections. One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." *In re Gorman*, 933 F.2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991).

As recently asserted in *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.* 411 F.3d 1332, 75 U.S.P.Q.2d 1051 (Fed. Cir. 2005), 35 U.S.C. §103 specifically requires an assessment of the claimed invention "as a whole." The "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner. In other words, 35 U.S.C. §103 requires some suggestion or motivation, before the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998).

In *KSR Int'l co. v. Teleflex Inc.*, 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court has acknowledged the utility of this "teaching, suggestion, motivation" inquiry when determining the obviousness of an invention by recognizing that the inquiry arose from "helpful insight" of the Court of Customs and Patent Appeals. The inquiry arose as a guard against a finding of obviousness where an examiner or a court was able to find all of the elements of an invention in the prior art, but without any suggestion or motivation to combine the prior art references that described the elements in question. The Supreme Court reiterated that "a patent composed of several elements is not proved obvious merely by

demonstrating that each of its elements was, independently, known in the prior art.” 167 L.Ed.2d at 14.

Furthermore, this “as a whole” instruction in 35 U.S. §103 prevents evaluation of the invention part by part, aided by the template of Applicants’ disclosure. Without this important requirement, an obviousness assessment might reduce an invention into its component parts, then find a reference corresponding to each component. This type of assessment would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. The U.S. Supreme Court cautioned against such analysis in *KSR*, stating, “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” (167 L.Ed.2d at 725, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (383 U.S., at 36, quoting *Monroe Auto Equipment Co. v. Heckthorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964))).

Finally, Uthoff and Kahn do not provide that which is missing from the other cited documents. As such, Applicants respectfully submit that each of the claims is not obvious. Applicants respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

### **Obviousness-Type Double Patenting Rejection**

The Examiner rejected claims 39 and 42-64 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54, 56-73, 75, and 79-88 of copending Application No. 10/219,398 in view of Neustadter et al. (U.S. Patent No. 3,565,387). It is noted that copending Application No. 10/219,398 has not yet issued.

This rejection is traversed, particularly in view of the above discussion of Neustadter et al.; however, in the event that the rejection is maintained it will be addressed upon an indication of otherwise allowable subject matter.

**Amendment and Response**

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**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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**CERTIFICATE UNDER 37 CFR 1.8-1.10:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being deposited with the United States Postal Service Express Mail Post Office to addresser's service under ~~transmitted by facsimile in accordance with 37 CFR 1.6(d)~~ to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21<sup>st</sup> day of August, 2007, at                      (Central Time). Express Mail mailing label number: EM 063174158 US.

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